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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,297	04/09/2007	Yusuke Nakamura	082368-007500US	6847

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EXAMINER

MI, QIUWEN

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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09/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,297	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Qiuwen Mi	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to a first method of diagnosing breast cancer or a predisposition for developing breast cancer in a subject.

Group II, claim(s) 17-19, 79, and 80, drawn to a breast cancer reference expression profile comprising a pattern of gene expression of two or more breast cancer-associated genes.

Group III, claim(s) 20, 23, 25, 28, 60, 63, 83, and 84, drawn to a second method of screening for a compound for treating or preventing breast cancer comprising the steps of contacting a test compound with a polypeptide by a polynucleotide etc.

Group IV, claim(s) 21, 22, 24, 26, 27, 29, 61, 62, 64, 85, 86, and 87, drawn to a third method of screening for a compound for treating or preventing breast cancer comprising the steps of contacting a test compound with a cell expressing one or more marker genes.

Group V, claim(s) 30, 31, 81, and 82, drawn to a kit/array comprising a detection reagent that binds to two or more nucleic acid sequences.

Group VI, claim(s) 32-34, 42-44, 65, 66, and 89, drawn to a fourth method of treating or preventing breast cancer in a subject comprising administering to a subject an antisense or siRNA composition.

Group VII, claim(s) 35-41, 45-51, 67-73, and 90-93, drawn to a fifth method of treating or preventing breast cancer in a subject comprising administering to a subject an antibody, or immunologically active fragment thereof.

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Group VIII, claim(s) 52, 53, 56, 57, 74, and 95, drawn to a first composition for treating or preventing breast cancer comprising a pharmaceutically effective amount of an antisense polynucleotide or siRNA against a polynucleotide.

Group IX, claim(s) 54, 55, 58, 59, 75, 76, 88, 94, 96, and 97, drawn to a second composition for treating or preventing breast cancer comprising a pharmaceutically effective amount of an antibody or fragment or compound.

Group X, claim(s) 77, and 78, drawn to a sixth method for predicting metastasis of breast cancer in a subject comprising the steps of detecting an expression level of one or more marker genes in a specimen, and calculating the magnitude of vote (Vi).

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As in Groups I-IX, calculating the magnitude of vote (Vi) is required as in Group X; in Group I-V, IX, and X, administering to a subject an antisense or siRNA composition is not required as in Group VI; in Group II, a breast cancer reference expression profile, administering to a subject an antibody is not required as in Group VII, therefore, there is no special technical feature in the application. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1, and therefore lack of unity of invention exists.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QIUWEN MI whose telephone number is 571-272-5984. The examiner can normally be reached on Monday through Friday: 8: 30 am to 5: 00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TERRY MCKELVEY can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Qiuwen Mi

/Patricia Leith/
Patricia Leith
Primary Examiner
AU 1655